

REMARKS

Applicants gratefully acknowledge the Examiner's withdrawal of the previously pending rejections. Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested.

Status of the claims

Claims 3-5 and 11-24 are pending in the application. Claims 3-5, 11, 15, 21 and are amended. Claims 3-5, and 21 are amended to add functional language to the claims regarding utility as a wax component in cosmetic and/or pharmaceutical compositions. Claims 11 and 15 are amended for clarity. Claim 21 is also amended to overcome the new matter rejection, as discussed below. Support is found throughout the substitute specification as originally filed. No claims are cancelled, and no new claims are added in the present action.

No new matter has been added.

Summary of the Invention as Claimed

As currently amended, one aspect of the claimed invention is drawn to a fatty acid ester mixture of pentaerythritol, wherein the fatty acid is a C6-C22 fatty acid or fatty acid mixture, or a mixture of C16 and C18 fatty acids, and wherein the ester mixture contains less than 0.3% by weight of esters containing C17 fatty acid acyl groups, and has a melting point of at least 30°C, **wherein the fatty acid ester mixture is useful as a wax component in cosmetic and/or pharmaceutical compositions** (claims 3-5 and 21-24). The fatty acid ester mixture contains monoesters, diesters and triesters (claim 4), and may also contain tetraesters (claim 5). In one embodiment of the invention as now claimed, the fatty acid esters **comprise** unbranched fatty acids (claims 21 and 24).

Another embodiment of the invention as now claimed is drawn to a cosmetic and/or pharmaceutical composition comprising the above wax ester mixture (claims 11-20).

Rejections under 35 U.S.C. § 112, first paragraph

Previously pending claims 3-5 and 11-24 were rejected under 35 U.S.C. § 112, first paragraph, as containing new matter. The phrase "C17 esters" was allegedly not supported in the application as originally filed, and therefore allegedly broadened the claims beyond the scope of the application as originally filed. Applicants do not agree with the Examiner on this point, and therefore traverse the rejection. The following is disclosed, *inter alia*, on page 3, lines 17-20, of the substitute specification as originally filed, as well as in original claim 1, now cancelled:

"Accordingly, the present invention relates to **esters** of C₆₋₂₂ fatty acids of pentaerythritol and/or dipentaerythritol, tripentaerythritol **which contain** less than 0.3% by weight **C₁₇ fatty acid acyl groups** and have a melting point of at least 30 °C." (substitute specification, page 3, lines 17-20, emphasis added)

It is clear throughout the specification that the subject matter of the invention is directed to wax **esters**. These wax esters are complex mixtures of species, both in terms of the fatty acid acyl groups (carbon-content of 6-22, branching, unsaturation) as well as the number of acyl groups which have reacted with the tetra-alcohol, pentaerythritol (1-4 acyl groups possible per pentaerythritol, as presently amended to limit the polyol to pentaerythritol only). The negative limitation with regard to C17 indicates that essentially no C17 fatty acids (<0.3%) were present in the mixture of fatty acids used to form the ester mixture. Therefore, it is proper to state the negative limitation in terms of the wax ester product containing less than 0.3% of C17 fatty acid acyl groups, since the products are esters.

If the Examiner continues to have questions regarding this point, an invitation is extended to contact the undersigned directly by telephone, at the telephone number indicated below.

Previously pending claim 21 was rejected under 35 U.S.C. § 112, first paragraph, as containing new matter with regard to the phrase "predominantly unbranched". In response, the claim has been amended to "comprises unbranched fatty acids", as supported on page 3, lines 22-26, of the substitute specification as originally filed.

In view of these amendments and remarks, the Examiner is respectfully requested to withdraw the new matter rejections.

Rejections under 35 U.S.C. § 103(a)

Claim 3, as previously presented, was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lindner (US 4,332,702) in view of Sakurai, et al. (US 4,113,635; "Sakurai"). Applicants respectfully traverse the rejection.

Lindner discloses partial esters of pentaerythritol useful as internal lubricating agents for lowering the viscosity of polyvinyl chloride resins, as well as hydrogen chloride scavengers. The fatty acid portion of the partial pentaerythritol esters comprises 0-10% C14, 0-5% C15, 30-60% C16, 0-5% C17, and 30-60% C18. The partial esters are 25-45% monoester, 40-60% diester, and 15-30% triester, being substantially free of the tetraester.

The Examiner acknowledged that Lindner's esters do not have applicants' claimed melting point of at least 30 °C. Therefore, the Examiner joined Sakurai.

Sakurai discloses rust-proof lubricant compositions for coating metals, comprising mono-, di- and tri- partial esters of pentaerythritol and fatty acids having more than 6 carbon atoms; melting points are stated by Sakurai to be in the range of 30-60 °C (col 1, lines 20-25). However, Sakurai makes the general statement that most of the partial esters of pentaerythritol and a fatty acid have melting points of less than 60 °C (col 3, lines 26-27). Note that the latter indicates the possibility of the partial esters being liquid at room temperature, i.e. having melting points below 30 °C, since only an upper limit is disclosed.

Applicants do not necessarily agree with the Examiner's characterizations of either Lindner or Sakurai. Lindner's utility is not in the cosmetic arts, instead being drawn to use as internal lubricants and HCl scavengers for polyvinyl chloride (i.e., plastic) compositions. Therefore, the disclosed utility of Lindner would not teach,

motivate or suggest to one skilled in the art that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions. Further, Sakurai is also totally unrelated to the cosmetic and/or pharmaceutical arts, but rather discloses compounds of use as rust-proof lubricant compositions for coating metals. Table 3 of Sakurai lists his products' activities of "degreasing ability", "rust preventiveness", "oil stain", and "press lubricity", none of which are even remotely related to the cosmetic or pharmaceutical arts. Therefore neither Sakurai nor the combination of Lindner and Sakurai teaches, motivates or suggests to one skilled in the **cosmetic/pharmaceutical arts** that their compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions.

In his summary statement, the Examiner observed that "an obviousness rejection based on similarity in chemical structure **and function** entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have **similar properties**" (Final Office Action, page 10, middle; emphasis added). Although applicants do not agree with the Examiner's statements, in order to further prosecution, the claims have been amended in a manner which overcomes the obviousness rejection. Thus, as presently amended, applicants now specifically claim cosmetic and/or pharmaceutical utility for their pentaerythritol fatty acid ester mixtures.

Therefore, on the basis of at least these two distinctions, the equivocal melting points disclosed for Sakurai's partial ester mixtures, and the silence of the cited art with regard to cosmetic and/or pharmaceutical utility, applicants' claims as presently amended define subject matter that is unobvious over the cited combination of art.

Claims 4 and 22, as previously presented, were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lindner in view of Sakurai. Applicants respectfully traverse the rejection.

Lindner and Sakurai are discussed above. Again, the difference between applicants' ester mixture and that of Lindner is acknowledged by the Examiner to be applicants' presently claimed melting point. Applicants do not necessarily agree with the Examiner's characterizations of either Lindner or Sakurai.

Again, Lindner's utility is not in the cosmetic arts, instead being drawn to use as internal lubricants and HCl scavengers for polyvinyl chloride (i.e., plastic) compositions. Therefore, the disclosed utility of Lindner would not teach, motivate or suggest to one skilled in the art that his compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions. Further, Sakurai is also totally unrelated to the cosmetic and/or pharmaceutical arts, but rather discloses compounds of use as rust-proof lubricant compositions for coating metals. Table 3 of Sakurai lists the activities of "degreasing ability", "rust preventiveness", "oil stain", and "press lubricity", none of which are even remotely related to the cosmetic or pharmaceutical arts. Therefore neither Sakurai nor the combination of Lindner and Sakurai teaches, motivates or suggests to one skilled in the **cosmetic/pharmaceutical arts** that their compositions would have any reasonable probability of success as components of cosmetic or pharmaceutical compositions.

In his summary statement, the Examiner stated that "an obviousness rejection based on similarity in chemical structure **and function** entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have **similar properties**" (Final Office Action, page 13, top paragraph; emphasis added). Although applicants do not agree with the Examiner's statements, in order to further prosecution, the claims have been amended in a manner which overcomes the obviousness rejection. Thus, as presently amended, applicants now specifically claim cosmetic and/or pharmaceutical utility for their pentaerythritol fatty acid ester mixtures.

Therefore, on the basis of at least these two distinctions, the equivocal melting points disclosed for Sakurai's partial ester mixtures, and the silence of the cited art with

regard to cosmetic and/or pharmaceutical utility, applicants' claims as presently amended define subject matter that is unobvious over the cited art.

Claims 5 and 23, as previously presented, were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sakurai, further in view of Knothe, et al. (American Chemical Society, 1997; "Knothe"). Applicants respectfully traverse the rejection.

As discussed above, Sakurai discloses rust-proof lubricant compositions for coating metals, comprising mono-, di- and tri- partial esters of pentaerythritol and fatty acids having more than 6 carbon atoms; melting points are stated to be in the range of 30-60°C. However, Sakurai makes the general statement that most of the partial esters of pentaerythritol and a fatty acid have melting points of less than 60°C (col 3, lines 26-27). Example 3 discloses a fatty acid pentaerythritol ester mixture that is 20% monoester, 30% diester, 40% triester, and 10% tetraester, whereas applicants' claim 5 discloses about 12-19% monoester, about 25-35% diester, about 30-40% triester, and about 6-11% tetraester. As noted by the Examiner, Sakurai fails to disclose explicitly that the fatty acid is a mixture of fatty acids. In order to cure this deficiency in Sakurai, the Examiner joined Knothe, which discloses the typical fatty acid composition of beef tallow.

As noted above, applicants now claim cosmetic and/or pharmaceutical utility for their fatty acid ester mixtures. With regard to Sakurai, the Examiner stated that "[a]ccording to the results in Table 3 the lubricant of Example 3 exhibited satisfactory results **for Applicants' intended purpose**" (Office Action, page 16, point 33; emphasis added). Applicants disagree with the Examiner's statement. It is noted that Sakurai's utility is not in the cosmetic or pharmaceutical arts, instead being drawn to use as rust-proof lubricant compositions for coating metals. Table 3 lists the activities of "degreasing ability", "rust preventiveness", "oil stain", and "press lubricity", none of which are related to the cosmetic or pharmaceutical arts. Therefore, Sakurai does not teach, motivate or suggest to one skilled in the cosmetic/pharmaceutical arts that his compositions would have any reasonable probability of success as components of

cosmetic or pharmaceutical compositions. There would have been no apparent correlation of Sakurai's rust-proof lubricating properties with applicants' cosmetic and/or pharmaceutical properties to one skilled in the art at the time of the invention.

Therefore the claims as presently amended are patentably unobvious over the cited art.

Previously pending claims 11-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barth et al. (US 2,441,555; "Barth"), in view of Memita et al. (WO 2002/22548, using US 6,939,980 as English translation; "Memita"), in view of Scheuffgen (US 4,868,220), in view of Plough, Inc. (EP 0179416; "Plough"), in view of Bauer et al. (WO 2003/028690; using US 2004/0258721 as English translation; "Bauer"), in view of Sakurai, and further in view of Kirk-Othmer (Wiley-Interscience, 1993, vol. 10, 4th ed., page 267; "Kirk-Othmer"). Applicants respectfully traverse the rejection. Applicants do not necessarily agree with the Examiner's characterizations of any of Barth, Memita, Scheuffgen, Plough, Bauer, Sakurai or Kirk-Othmer.

Barth discloses a process for preparing **tetraesters** of pentaerythritol with fatty acids containing 10 or more carbon atoms. Thus, an initially prepared monoester is further reacted with a different acid or anhydride (e.g. acetic anhydride) to form the fully esterified **tetraesters**. These product tetraesters are listed in Table I, together with their physical properties and starting materials. The melting point of 36-38 °C quoted by the Examiner is for the **tetraester**, pentaerythritol triacetate monostearate (Table 1, first entry). Further, the physical data reported are for the full **tetraesters** and are therefore unrelated to applicants **partial ester** mixtures.

Further, the esters of Barth are reported to be useful in the plastics and coatings fields as modifiers, which are clearly unrelated to cosmetic and/or pharmaceutical utility as presently claimed by applicants. Thus, the disclosed utility of Barth would not teach, motivate or suggest to one skilled in the art that his compositions would have any

reasonable probability of success as components of cosmetic or pharmaceutical compositions.

Barth also fails to teach pentaerythritol ester mixtures containing monoester, diesters and triester in various ratios. His synthesis method clearly discloses methods or preparing **monoesters** with fatty acids of 10 or more carbons, which is followed by reaction with acetic acid to form the full **tetraesters** comprising 3 acetate groups. This is in stark contrast to applicant's complex mixture of esters having acyl groups of varying carbon content, as well as mono-, di-, tri-, and tetra-ester species. Both Barth's intermediate monoesters as well as his ultimate product tetraesters comprising one fatty acid acyl group and three acetate groups, are outside the scope of applicants' partial ester mixture. In particular, applicants' claims do not encompass a C2 (acetate) acyl group. Further, there is no indication that a product as divergent as Barth's, versus applicants' product, would have any utility whatsoever in the cosmetic and/or pharmaceutical arts, based on Barth's disclosure.

The Examiner has made the following statement:

"Furthermore, the phrase "at least one C6-22" has been interpreted to denote that the pentaerythritol ester mixture can be a monoester, diester, triester or tetraester or mixtures thereof; and **one** of the fatty acids esterified to produce the mixture is selected from the group of fatty acids with carbon atoms numbering from 6-22." (Final Office Action, page 20, middle; emphasis added)

It appears that the Examiner is interpreting applicants' claim to read that the **mixture** may be a mono- **or** di- **or** tri- **or** tetra-ester. As far as this is the case, applicants argue that the substitute specification clearly teaches that the claimed composition must comprise a wax ester **mixture**, and cannot be either a monoester **or** a diester **or** a triester **or** a tetraester. See, specifically, claim 12. In order to clarify this point, claim 11 has been amended to indicate that one or more fatty acids selected from the group consisting of C6-22 fatty acids and combinations thereof is used as the acid component for preparing the pentaerythritol ester mixture.

The Examiner noted that the differences between Barth and applicants' claimed processes include the lack in Barth of specific disclosure regarding (1) utility in cosmetic

and/or pharmaceutical compositions, (2) wax components, non-ionic surfactants and oil components, (3) partial glycerides, and (4) mixtures of mono-, di-, tri- and tetra-esters in specific ratios. In order to cure the substantial deficiencies noted in Barth, the Examiner joined Memita, Scheuffgen, Plough, Bauer, Sakurai and Kirk-Othmer.

Memita discloses a general process for producing an ester, comprising reacting an alcohol or polyol with a C5-C30 carboxylic acid to obtain a crude esterified product, adding 5-100 parts of a hydrocarbon solvent per 100 parts of crude ester, and neutralizing with an aqueous alkali solution. The polyol can be pentaerythritol.

However, the described esters are fully esterified **tetraesters** as clearly disclosed in Memita's Examples. The pentaerythritol esters disclosed in Examples 1, 2 and 24-26, as well as their corresponding comparative examples, are all prepared with a reaction stoichiometry of >4:1 acid:pentaerythritol, and the product esters are all characterized by low hydroxyl values, which demonstrates that the free OH content of the products is low (i.e. the product esters must be **tetraesters**). Thus, the products of Examples 1 and 2 have hydroxyl values of 0.8 mg KOH/g and 1.5 mg KOH/g, respectively. Specifically, the compounds of Example 2 and Comparative Example 2, cited by the Examiner, were prepared with a 4.125:1 ratio of (total stearic plus palmitic) acid:pentaerythritol, and both products have hydroxyl values of 1.5 mg KOH/g. As such, the compounds cited by the Examiner, of mp 67.7°C and 63.4°C are **tetraesters**. Nowhere in Memita is there disclosure of a **mixture of partial esters of pentaerythritol**, as presently claimed by applicants.

Scheuffgen discloses a lanolin substitute comprising 40-60% of a mixture comprising about equimolar amounts of a **difatty acid ester** of pentaerythritol and a difatty alcohol citrate, in combination with mono- and diglycerides of oleic acid, mono and diglycerides of palmitic and stearic acids, and an adduct of 3-7 ethylene oxides onto a vegetable sterol. Scheuffgen teaches only **diesters** in his lanolin substitute, in contrast to applicants' complex mixture of mono-, di-, tri- and tetra-esters.

Plough and Bauer both are drawn to fully esterified **tetraesters**, and are therefore unrelated to applicants' **partial ester** mixtures as presently claimed. Examples 93, 94 and 96 of Bauer (p. 46), disclose pentaerythritol **tetra**isostearate. Also, Plough discloses "pentaerythritol **tetra** (C20 – C24) aliphatic hydrocarbon carboxylates" (page 2, bottom paragraph). In contrast, applicants' claims are drawn to fatty acid **partial ester mixtures**, with specific ranges of mono-, di-, tri-, and tetra-esters. Therefore Plough and Bauer are unrelated to applicants' presently amended claims, and cannot cure the substantial deficiencies of Barth disclosed above.

Further, even if the pentaerythritol tetraesters of Plough were relevant art, which they are not as discussed above, applicants' previously submitted declaration disclosed comparative testing of a composition of the present invention versus a composition comprising the preferred tetraester as specifically taught by Plough, pentaerythritol tetrabehenate (Plough, page 3, top paragraph; all Examples). As clearly demonstrated by the comparative data in the previously submitted declaration, the ester mixture of the present invention provides a useful and stable cosmetic emulsion, whereas the comparison tetraester of Plough does not (emulsion separated). Thus the ester mixtures and compositions of applicants are distinguished over the cosmetic cited art, and are patentably unobvious.

The Examiner also joined Sakurai, which discloses a mixture of pentaerythritol partial esters useful as rust-proof lubricants, not as a component of cosmetic and/or pharmaceutical compositions. Sakurai is unrelated to the cosmetic arts, but rather discloses compounds of use as rust-proof lubricant compositions for coating metals. Sakurai is further discussed above.

In summary, the Examiner has failed to provide a *prima facie* case of obviousness using the above-cited combination of references. Therefore, applicants' cosmetic and/or pharmaceutical composition claims, as presently amended, define unobvious subject matter over the cited art.

Previously pending claims 21 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sakurai in view of Kirk-Othmer. Applicants respectfully traverse the rejection.

Sakurai is discussed above.

Kirk-Othmer was joined for the composition of coconut oil fatty acids.

As presently amended, claim 21 recites that the C6-C22 fatty acid **comprises unbranched** fatty acids. There is no such limitation in Sakurai. Also, there is no particular carbon limitation for the fatty acids disclosed in Sakurai, although embodiments of specific fatty acids are provided in the Examples. Indeed the fatty acid disclosure of Sakurai is so broad as to teach one skilled in the art at the time of the invention that this feature is not particularly important, which would be reasonable for an industrial lubricant.

Further, it is noted that Sakurai is also silent regarding applicants' negative limitation for the C17-containing ester component. Indeed, none of the references cited by the Examiner teach or suggest, either explicitly or inherently, the specific negative limitation on C17 acyl groups that applicants claim.

In conclusion, the limitations of applicants' claims 21 and 24 as presently amended are not taught by the combination of cited references. Therefore applicants' claims as presently amended are novel and patently unobvious over the cited art.

Conclusion

In summary, in view of the above claim amendments and remarks, applicants believe that the pending claims as amended are in condition for allowance. The Examiner is respectfully requested to enter the amendments, reconsider, withdraw the rejections and allow the claims.

If any additional fees are required in support of this application, authorization is granted to charge our Deposit Account No. 50-1943.

Respectfully submitted,

Date: May 3, 2010

/Robert N. Henrie II/
Robert N. Henrie II
Reg. No. 60,581
Fox Rothschild LLP
2000 Market Street; 20th Floor
Philadelphia, PA 19103-3222
Tele: (215) 299-2000
Direct: (215) 299-2904
Fax: (215) 299-2150